#### **Public Comment on the**

CASAC Review of EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019)

# CASAC Should Acknowledge that the Scientific Review of the Ozone National Ambient Air Quality Standards is Undermined by Ad Hoc Changes to the Review Process

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I am a past chair of the U.S. Environmental Protection Agency's Clean Air Scientific Advisory Committee (CASAC) and chaired the CASAC Ozone Review Panel from 2012 to 2014.

## Changes Since 2017 Undermine the Quality, Credibility, and Integrity of NAAQS Review

On December 2, 2019, I and 17 other members of the former CASAC Ozone Review Panel provided comments to CASAC regarding process deficiencies imposed on the National Ambient Air Quality Standard (NAAQS) review process by EPA Administrators Pruitt and Wheeler.<sup>1</sup> The members of the former CASAC Ozone Review Panel stated:

We unanimously find that myriad unwarranted changes have been made to the NAAQS review process and to the composition of the CASAC since 2017. These changes are collectively harmful to the quality, credibility, and integrity of EPA's scientific review process and to CASAC as an advisory body. These changes have been made without advance notice to, or input from, the CASAC, cognizant EPA staff, or the public.

The members of the former panel further stated: "These changes should be reversed. The NAAQS review for ozone should be suspended until these deficiencies are corrected."

The former members of the CASAC Ozone Review Panel summarized the changes to the NAAQS review that undermine the quality, integrity, and credibility of the ozone review as follows:

Since 2017, EPA has made the following changes to the NAAQS review process and to the chartered CASAC, all of which have undermined and compromised the process: (1) CASAC appointment criteria emphasize geographic location and not scientific expertise; (2) CASAC appointment criteria emphasize government affiliation and not scientific expertise; (3) CASAC appointment criteria ban nongovernmental but not governmental recipients of EPA scientific research grants; (4) complete turn-over of CASAC membership; (5) the CASAC PM Review Panel was disbanded; (6) there was refusal to form an Ozone Review Panel for which nominations had already been solicited; (7) a "pool" of consultants was

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<sup>&</sup>lt;sup>1</sup> Frey, H.C., A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, J.S. Ultman, K.C. Weathers, P.B. Woodbury, and R. Wyzga, Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), Letter to EPA Administrator Andrew Wheeler from members of the former Clean Air Scientific Advisory Committee Ozone Review Panel (2009-2015), December 2, 2019. <a href="https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/\$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf">https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/\$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf</a>

formed with serious shortcomings of expertise and an inability to deliberate; (8) compressed the scientific review into a timeframe that results in lack of transparency, in part, by reducing opportunities for public comment; (9) eliminated revised external review drafts of complex scientific documents; (10) eliminated planning for the risk and exposure assessments; (11) eliminated separate risk and exposure assessment documents for external review; (12) commingled policy with science by producing and reviewing policy and science assessments concurrently; and (13) provided an unrealistically short time period for public review and comment on the draft ozone Policy Assessment

Yet, there is no mention in CASAC's draft letters on either the EPA's draft Integrated Science Assessment (ISA) or draft Policy Assessment (PA) that members of the former CASAC Ozone Review Panel have provided consensus comments on these points. CASAC fails to explicitly acknowledge these process deficiencies in its draft letter on the draft ISA. CASAC acknowledges some, but not all, of these process deficiencies in its draft letter on the draft PA. The full set of process deficiencies should be addressed in both letters.

## CASAC Lacks Breadth, Depth, and Diversity of Expertise, Experience and Perspectives Needed for NAAQS Review

The current seven-member CASAC does not have the breadth, depth, or diversity of expertise, experience, and perspectives needed for the ozone review, nor could any group of this size cover the needed scientific disciplines. However, CASAC fails to acknowledge this in its draft letters on the draft ISA and draft PA. CASAC does not offer any caveat that it is unable to fully advise EPA regarding the draft ISA and draft PA because it lacks expertise in key areas (e.g., measurement of ozone air quality, exposure assessment, epidemiology), and lacks diversity of perspectives, expertise and experience in all areas.

As stated by the former members of the CASAC Ozone Review Panel:

Although a smaller "pool" of consultants was recently appointed to support the CASAC,<sup>2</sup> the pool is not focused on ozone in that there is not adequate breadth, depth, and diversity of scientific expertise and experience needed for the ozone review, interacts with the CASAC only in writing, and is not allowed to deliberate with the CASAC; therefore, the pool does not adequately or appropriately substitute for an Ozone Review Panel. An Ozone Review Panel should be appointed to provide CASAC with the expertise it needs.

<sup>&</sup>lt;sup>2</sup> EPA, "Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts," News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019. https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts

CASAC should acknowledge this in its letters on the draft ISA and the draft PA.

#### The Ozone Review Process Has Been Truncated and Accelerated

Furthermore, the scientific review for the ozone NAAQS has been truncated and accelerated. Coupled with changes to the composition of CASAC and the failure to appoint an ozone review panel, the accelerated schedule has undermined the quality, integrity, and credibility of the NAAQS review process. As stated by former members of the CASAC Ozone Review Panel:

The late 2020 deadline for completing the ozone review does not provide sufficient time to complete the "thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" mandated by the Clean Air Act for the review of NAAQS. This would be true even if the committee were supported by a robust panel of experts in the multiple disciplines involved. Thus, EPA is ignoring statutory requirements for the need for a thorough and accurate scientific review of the NAAQS in setting a review schedule. Statutory deadlines are not an excuse for deficiencies in the review process.

CASAC should acknowledge this in its letters on the draft ISA and the draft PA.

The former members of the CASAC Ozone Review Panel also found the following:

Truncating the scientific review schedule by deleting key steps in the review process, such as by deleting assessment documents and deleting revised external review drafts of assessment documents, leads to fewer CASAC public meetings and, therefore, fewer opportunities for public comment. Fewer opportunities for public comment creates a less transparent NAAQS scientific review process.

CASAC should advise the Administrator that the rushed review schedule leads to a less transparent process.

## The Ozone Review Inappropriately Commingles Policy and Scientific Assessments

The former members of the CASAC Ozone Review Panel noted that:

A key principle of the 2006 revisions to the NAAQS review process, which were modified in part in 2007 and 2009.<sup>3,4,5</sup> is that the scientific foundation

<sup>&</sup>lt;sup>3</sup> Peacock, M., "Process for Reviewing National Ambient Air Quality Standards," Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006.

Peacock, M., "Modifications to Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, April 17, 2007

Jackson, L., "Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009. https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf

of the review must be established before addressing policy issues. Failure to do this risks commingling policy issues prematurely before the science issues are adequately vetted and settled, which in turn creates the potential for policy choices to be made irrespective of the science. Thus, the integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled.

The former members of the CASAC Ozone Review Panel concurred with members of the disbanded CASAC Particulate Matter Review Panel that such commingling is inappropriate:

We concur with the October 22, 2019 report of the Independent Particulate Matter Review Panel (IPMRP) (formerly the CASAC PM Review Panel) that "EPA should not be producing a Policy Assessment in advance of first finally determining what the science being assessed is – i.e. prior to finalizing the ISA." We agree with the IPMRP that "to do otherwise puts the cart before the horse."

#### It is Not Appropriate for CASAC to Offer Advice Outside of Its Expertise

On numerous occasions, some members of CASAC, and especially the CASAC chair, have opined that it is useful for the reconstituted CASAC, deprived of appropriately constituted review panels, to offer whatever advice it can despite its limitations. However, as noted by former members of the CASAC Ozone Review Panel:

However, CASAC lacks the breadth, depth, and diversity of expertise and experience necessary to fully consider the full range of salient issues. The Clean Air Act does not specify that the NAAQS review may be partial or incomplete. It requires that "Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." This is why, for four decades, CASAC has been augmented with expert review panels, such that it would have the breadth, depth, and diversity of expertise and experience to fulfill the statutory requirement for the scope of scientific assessment. CASAC must be

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Frey, H.C., P. Adams, J.L. Adgate, G. Allen, J. Balmes, K. Boyle, J.C. Chow, D.W. Dockery, H. Felton, T. Gordon, J.R. Harkema, J. Kaufman, P. Kinney, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and R. Wyzga, "Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC Particulate Matter Review Panel) on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)," 11 page letter and 192 pages of attachments submitted to Hon. Andrew Wheeler, Administrator, Docket ID No. EPA-HQ-OAR-2015-0072, and Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, October 22, 2019 https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/\$File/Independ ent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf

augmented with an Ozone Review Panel to be able to discharge its duties under the law.

I provided detailed written and oral comments to CASAC on December 4 and 5, 2019, regarding the ozone NAAQS review.<sup>7,8,9</sup> My oral comments and written statement on December 4 highlighted the points raised by former members of the CASAC Ozone Review Panel in its December 2, 2019 consensus letter.

#### **CASAC Must Consider At-Risk Populations**

My oral and written statement on December 5, 2019 regarding CASAC's review of the draft PA emphasized the following:

- 1. CASAC must consider at-risk populations in arriving at its advice.
- 2. There is a key role for expert judgment in arriving at advice regarding the effect of ozone on at-risk populations. This is because direct empirical evidence regarding at-risk populations is lacking.
- 3. For example, controlled human studies are typically the key foundation of the evidence-based approach of the Policy Assessment. Yet, such studies cannot be done on the most sensitive or at-risk subpopulations, e.g., severely asthmatic subjects, for ethical reasons and, thus, there is absence of direct evidence for many at-risk groups of policy-relevance. This does not mean that CASAC may ignore such subpopulations.

I stated: "Given the important role of expert judgment in this review, it is critical that CASAC have the breadth, depth, and diversity of expertise and experience needed to condition such judgment in an unbiased. manner. This cannot happen given the current size and composition of this group, and is why an ozone review panel is needed." CASAC has failed to acknowledge this point.

#### **CASAC May Not Redefine the Decision Context of NAAQS Review**

I also stated: "Statements by the chair that he and the administrator share a view of 'sound science' are ideological statements aimed at raising the burden of scientific evidence above that required by statute, or ignoring evidence altogether. Congress, not CASAC, and not the Administrator, has defined the decision context for NAAQS review

Frey, H.C., <u>The NAAQS Review Process for Ozone Should be Suspended Until Process Deficiencies are Corrected</u>, Oral and Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 4, 2019

Frey, H.C., Review of the Draft Policy Assessment for Ozone Must Be Properly Conditioned and Unbiased, Consistent with the Decision Context Set Forth by Congress, Oral and Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 5, 2019, 3 pages

<sup>&</sup>lt;sup>9</sup> Frey, H.C., <u>The NAAQS Ozone Science Review Process is Broken and Not Credible: EPA Should Start Over</u>, Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 5, 2019, 37 pages.

as set forth in the Clean Air Act." I have repeatedly advised CASAC to "ask the EPA Office of General Counsel for advice regarding the decision context of the NAAQS review." 10,11 Yet, CASAC has not done this. CASAC's draft letters indicate that CASAC as a group does not understand the decision context of the NAAQS. CASAC may not substitute a risk-seeking requirement for near scientific certainty as a basis for finding that standards do not need to be revised, because such a risk attitude is not consistent with the Clean Air Act. CASAC, and its members, may not impose their normative personal values over that of the decision context that has been set forth under the Clean Air Act.

I expounded on these key points in a detailed, 37 page written statement that addressed:

- Numerous Ad Hoc and Inappropriate Changes to NAAQS Review
- Causality Determination Framework
- Chartered CASAC Lacks Breadth, Depth, and Diversity of Expertise and Experience Needed for the Ozone NAAQS Review
- The Unprecedented Ad Hoc Creation of a Pool of Consultants
- Refusal to form an Ozone Review Panel is Inconsistent with Four Decades of Precedent
- Decision Context for NAAQS Review May Not Be Redefined by CASAC
- The Role of Expert Judgment in Scientific Review of the NAAQS
- 'Sound Science', CASAC, and Science Denial

With regard to the latter, typical "sound science" tactics aimed at raising the burden of proof beyond statutory requirement, or simply obfuscating, include but are not limited to the following:

- Insistence on re-definition of widely accepted terminology.
- Claiming and insisting that existing inference methods are "technically unsound" while positing that only a new method or group of methods, not actually demonstrated in the subject matter domain, must be used to arrive at valid inferences.

Frey, H.C. "Clarifying Oral Comment," to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Crystal City, VA, December 13, 2018. https://yosemite.epa.gov/sab/sabproduct.nsf/0471352D965DF693852583620007AEA3/\$File/List+of+sp eakers-121218-clarifying+comments.pdf

See also an article published December 14, 2018 by InsideEPA, "Former CASAC Chairman Warns 'Joke' Review Hurts PM NAAQS Assessment"

Frey, H.C., "The Clean Air Act, Not CASAC, Defines the Decision Context of the National Ambient Air Quality Standards," Public Comment to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, at its public meeting on Thursday, October 24, 2019 in Cary, NC.

https://yosemite.epa.gov/sab/sabproduct.nsf/A784C7989417F8C5852584AC00602A11/\$File/Oral+Statement+from+Chris+Frey+191024.pdf

- Demanding that each and every study be subject to highly restrictive "study selection" and "study evaluation" criteria, which would have the effect of throwing out each study one by one, after which a claim would be made that there are few/no acceptable studies and, hence, nothing new and no need to make any changes to existing regulations. This is in contrast to a more balanced approach in which studies are considered with regard to their strengths and limitations, recognizing that shortcomings of one study might be addressed by other studies and that, collectively, they provide a body of evidence useful for making inferences.
- Repeatedly citing one's own work or other fringe papers.
- Over-emphasizing/exaggerating uncertainties.

In my December 5, 2019 detailed written statement I point out that:

Other examples of "sound science" tactics go beyond claims about the science itself to process issues. For example, if one wanted to design a "science review" process that would lead to a predetermined outcome – in this case that there should be no change to the Ozone NAAQS – one would likely do the following (this list is illustrative, not exhaustive):

- Get rid of actual experts. Actual experts are a threat to a
  predetermined agenda because they will follow the science. Thus: (1)
  disband an expert panel, such as the CASAC PM Review Panel or
  refuse to form an expert panel, such as a CASAC Ozone Review
  Panel that has the breadth, depth, and diversity of expertise and
  experience to conduct a review; and (2) completely replace all of the
  existing members of the statutory advisory body, CASAC, using new
  criteria based on geographic location and governmental affiliation,
  rather than scientific expertise. Add to this a ban on nongovernmental
  recipients of EPA research grants.
- Require EPA staff to create assessment documents on an accelerated schedule.
- Not allow second external review drafts of the assessment documents, even if scientific revisions are warranted.
- Delete key assessment documents, such as the Risk and Exposure Assessment planning document and the first and second external review drafts of the Risk and Exposure Assessment.
- Release and review a draft PA before the draft ISA has been finalized, thereby commingling policy and science issues.
- Reduce the number of public meetings of the CASAC, which reduces opportunities for public comment and leads to a less transparent process.
- After criticism for disbanding the CASAC PM Review Panel and refusing to form an Ozone Review Panel, appoint an ad hoc pool of consultants by the politically appointed EPA Administrator rather than

the SAB Staff Office, including consultants nominated by the CASAC Chair whose advice is subject to cherry-picking.

## Comments on CASAC's Draft Letter on EPA's Draft Integrated Science Assessment

#### Letter

- CASAC should begin the letter by acknowledging that it lacks the breadth, depth, and diversity of expertise, experience, and perspectives to provide the scope and depth of review of the primary and secondary ozone standards and that this situation is because the EPA Administrator declined to appoint an appropriately constituted CASAC Ozone Review Panel.
- CASAC should caveat its letter by pointing out that, without the needed breadth, depth, and diversity of expertise, experience, and perspectives, it cannot credibly provide advice on issues that are outside its domain areas of expertise. An example is epidemiology.
- Furthermore, even in areas for which CASAC has some expertise, such as
  controlled human studies, toxicology, and ecological effects to wildlife, it lacks
  diversity of expertise, experience, and perspectives that comes from having
  multiple experts in key areas. This is not a limitation of any individual member of
  CASAC. Rather, this is a process limitation inappropriately imposed on CASAC
  by the EPA Administrator.
- As a matter of credible professional practice, an advisory group such as CASAC should acknowledge its own limitations before attempting to develop advice that it is not adequately constituted to give.
- Page 1, lines 33-36: The statement that the draft ISA "does not provide a comprehensive, systematic assessment of the available science relevant to understanding the public health impacts of changes in ambient concentrations of ozone" is nonsense. While the draft ISA has limitations and should be revised, it is in fact a first draft of available science according to the ground rules established in the Integrated Review Plan. In fact, CASAC's comments indicate largely concordance with much of the key findings of the draft ISA, challenging the draft ISA causality determinations for only a few endpoints. If the draft ISA were as deficient as CASAC implies here, CASAC would have found much more to quibble over than it has.
- Page 2, lines 1-3: the judgments regarding causality determination are judgments: i.e. they <u>are</u> subjective. Always have been. Nothing new in this. What has been demanded of EPA by previous CASAC review panels is that EPA clearly explain the basis of these judgments so that others can independently assess whether they concur with such

- judgments. **This is called peer review**. This is why the draft ISA has to be reviewed by a panel with the breadth, depth, and diversity of expertise, experience, and perspectives relevant to a critical review of the subject matter, not a smaller group cherry-picked by the Administrator.
- CASAC has identified some legitimate scientific concerns with some of the
  causality determinations (e.g., related to metabolic effects). These are
  outside my own expertise, so I cannot comment on whether CASAC is
  right or wrong with regard to its own judgments. I can comment that
  CASAC lacks the breadth, depth, and diversity of expertise, experience,
  and perspectives related to metabolic effects to go very far with advice on
  this matter.
- Page 2, lines 7-9: "The CASAC recommends that the EPA seek help from external experts in relevant areas, e.g., via the National Academies, to strengthen and clarify its framework for causal inference." There is nothing wrong with getting more input on the overall framework. However, CASAC states later that such advice should come from persons who do not have expertise in air quality. This is a mistake. This mistake is illustrated by a statement that EPA Administrator Wheeler made to the EPA Science Advisory Board that "federal research would be more accepted by the public if you used the double-blind standard for everything." This is an absurd statement in the context of air pollution epidemiology in that it is simply not possible to do a randomized controlled trial (RCT). Having experts on methodology without the ability to interact with domain experts in air quality is a sure-fire way to arrive at a methodology that is unworkable and irrelevant. Doing so would serve to obfuscate and delay, rather than enhance and enlighten.
- Page 3, line 34 and related: The CASAC appears, repeatedly, to fail to understand the role of the Integrated Review Plan (IRP) and the draft ISA. It is not the goal of the draft ISA to do new analyses. Thus, it is not the role of the ISA to "include these adjustments when applying epidemiology C-R functions to their risk assessments." The ISA does not do any risk assessments.
- Page 4, lines 9-15: While the consensus statements on welfare effects
  are well-written and appear to be well-considered, the CASAC should
  acknowledge that only one member of the chartered CASAC has relevant
  domain expertise with regard to ecological effects. In the last review,
  there were multiple experts for effects on plants, but there are none in this
  review. It is a valid and important point that the effects of ozone on wildlife
  are not assessed, and this should be included in future reviews.

https://thehill.com/opinion/energy-environment/449465-how-epa-administrator-wheeler-completely-misinterprets-science

- Page 4, line 21: CASAC makes many throw-away statements such as "to many expert readers." This is an appeal to vagueness and an appeal to authority. Such statements beg the question as to which expert readers is CASAC referring specifically? Did CASAC do a survey of expert readers? If the material is unclear to this CASAC, then delete "to many expert readers." If the material is unclear to 3 members of the ad hoc pool of consultants or to 2 public commenters, then specify. Do not overgeneralize.
- The letter fails to mention the compositional and process deficiencies that undermine the quality, integrity, and credibility of the review process. The Administrator should be advised of the limitations imposed on CASAC and the NAAQS review process and that these should be corrected.
- CASAC should recommend that an Ozone Review Panel be appointed by the EPA SAB Staff Office prior to review of the second draft of the ISA.

#### **Consensus Statements**

- Page 2, lines 39: "Multiple readers" is a vague appeal to authority that is unsubstantiated. Later text indicates some specific concerns raised perhaps by only a few members of the CASAC and only a few members of the ad hoc pool. Avoid appeals to vagueness and appeals to authority, and especially vague appeals to vague authority.
- Page 3, line 3: As an observation, nonlinearity below 40 ppb, if it does exist, is not likely to be particularly policy-relevant with regard to the evidence-based approach used later in the policy assessment.
- Page 3, line 7, the word "trustworthy" is used here, and in several other
  places, which seems to impugn the EPA staff. This also begs the
  question of who is making claims that others are not "trustworthy" and are
  these claims coming from a trustworthy source. Should not use this word.
  If there are specific concerns, then by all means state and explain them.
- Page 3, line 16: statistical significance is not necessarily a controlling factor in assessing elements of the overall body of evidence. This statement by itself is not particularly meaningful without additional context.
- Page 3, lines 39-40. The CASAC appears to be opining that temperature is an omitted control for ozone concentration-response. Yet, CASAC lacks breadth, depth, and diversity of expertise, experience, and perspectives regarding epidemiology. This is an example for which CASAC advice may not be trustworthy.
- Page 4, line 21: another claim that the draft ISA is not "trustworthy."
   Considering that this CASAC lacks breadth, depth, and diversity of expertise, experience, and perspectives, it is not clear that CASAC's claim that the draft ISA is not trustworthy is itself trustworthy.

- Page 4, line 23: "As noted by multiple external experts and in public comments": who, exactly? This is a vague appeal to authority. This vague statement is potentially highly misleadingly implying a wide-ranging vast authority when in fact such comments may be coming from either a very few number of people or from people who may have motivational biases. If CASAC wants to say that "the draft ISA appears to be biased toward defending EPA's methods and conclusions rather than providing a neutral, accurate, comprehensive review and summary and critical analysis and synthesis of available scientific studies," then CASAC should so state, and justify its statement based on evidence and logical inference, without appealing to a vague unspecified authority. This statement is not explained or justified, and thus seems like an unsubstantiated opinion of perhaps only a few members of CASAC.
- Page 4, lines 27-29: "The Draft Ozone ISA does not usefully summarize, or critically evaluate, available scientific information on whether or to what extent reducing ozone reduces public health risks." This CASAC lacks breadth, depth, and diversity of expertise, experience, and perspectives upon which to base such sweeping judgments.
- The statement above raises the question of motivational biases on the part of some members of the CASAC, who have made strong public statements previously. For example, in a 2015 Wall Street Journal editorial, the now-chair of CASAC stated that there are not adverse effects from exposure to ozone and, furthermore, that the current ozone standard will lead to "millions of lost jobs." The latter claim was based on a non-peer reviewed industry-funded study that has been roundly debunked, with some experts characterizing the study as being based on "fraudulent" assumptions. 14
- Page 5, lines 15-32: Much of this material reveals lack of understanding
  of the Integrated Review Plan and the role of the ISA. The ground rules
  for how systematic review in the ISA are done are given in the IRP. The
  ISA follows an approach for systematic review consistent with the IRP. It is
  not the role of the ISA to conduct new analyses and never has been.
- Page 7, lines 20-30: As clearly stated by the Court of Appeals for the
  District of Columbia in its August 2019 decision on the 2015 ozone
  standard, background concentration cannot be considered in setting a
  health protective standard. CASAC should make clear that it understands
  this. Feasibility of meeting a 70 ppb or any other standard is not relevant
  in setting a standard. Of course, CASAC should advise the Administrator
  regarding background levels but needs to put this in proper context.

<sup>13</sup> Cox, T., "The EPA's Next Big Economic Chokehold," Wall Street Journal, September 2, 2015.

<sup>&</sup>quot;Experts: Pro-Smog Pollution Report Is "Unmoored From Reality"," <a href="https://www.mediamatters.org/wall-street-journal/experts-pro-smog-pollution-report-unmoored-reality">https://www.mediamatters.org/wall-street-journal/experts-pro-smog-pollution-report-unmoored-reality</a>

- Page 9, line 19: "large amount" is vague. Not sure what is meant by "large." Note that CASAC has no experts in exposure assessment relevant to a stochastic population-based model such as APEX.
- Page 9-10, lines 35 (page 9) to 10 (page 10): These are interesting points. They would be stronger and more credible if they were from the results of interactive deliberations with an appropriately constituted CASAC Ozone Review Panel.
- Page 10, lines 41-42: regarding factors other than copollutants -- same comment. This point would be stronger and more credible if it was from the results of interactive deliberations with an appropriately constituted CASAC Ozone Review Panel.
- Page 1, line 39: Lange is a co-author of McCant et al., 2017. Did CASAC follow its own practices of having co-authors recuse themselves from deliberations on their studies?
- Page 12, line 3: "The non-member consultants also generally agreed that..." This statement implies that a majority of the ad hoc pool of consultants agreed on this point. Is this an accurate, trustworthy statement? CASAC should avoid vague appeals to authority and should make statements that are accurate and trustworthy. CASAC can avoid vagueness by making more specific, accurate, and trustworthy statements.
- Page 13, lines 17-19: Lack of availability of directly-relevant data does not, however, imply that there should be lack of consideration of potential at-risk populations.
- Page 14, line 1: "The conclusion of interest is whether people with asthma
  are more sensitive or not." While agreed that EPA should be clear as to
  what conclusions can be drawn, it can be useful to know "that individuals
  with asthma were at least as sensitive to acute effects of ozone as healthy
  individuals" if there is not stronger evidence to make the statement that
  CASAC appears to be looking for. Also, absence of evidence is not
  evidence of absence.
- Page 16, lines 11-19: The CASAC would benefit from deliberations with experts in epidemiology, who could explain the distinction between population and individual thresholds and why populations might not have thresholds even if individuals in the population do. Given that CASAC lacks breadth, depth, and diversity of expertise, experience, and perspectives regarding epidemiology, CASAC is especially not well qualified or positioned to offer advice on this matter.
- Page 16, line 43: goodness-of-fit should not be the only criterion for evaluating the suitability of a model.

- Page 18, lines 39-40: this is an interesting point that merits attention by EPA.
- Pages 22-35 regarding ecological effects: This material is very well-written and organized. It appears that the burden of the ecological effects review fell onto one expert member of the CASAC, who did a commendable job. In prior review cycles, reviews of ecological effects have been shared by multiple experts. The CASAC should advise the Administrator of the need to engage multiple domain experts in each major area pertaining to a review cycle. In the case of ozone, ecological effects are a major area for which there should be multiple domain experts as part of an ozone review panel that augments the chartered CASAC.
- Page 35-36, regarding ozone and climate change. The material here generally seems reasonable. However, CASAC lacks experts in the interaction between ozone and climate change, and should acknowledge this.
- Pages 36 pertaining to the PECOS tool and related issues: The relevant point here is whether EPA followed the Integrated Review Plan in developing the draft ISA. Largely, it appears that EPA did so. CASAC should acknowledge that the EPA staff were tasked with preparing the draft ISA under a highly compressed schedule. Detailed context-specific questions about study selection and interpretation are why there should be peer review by an external group of experts with the appropriate breadth, depth, and diversity of expertise, experience, and perspectives. Unfortunately, decisions by the Administrator have deprived CASAC of the experts needed for this review. Thus, CASAC lacks the breadth, depth, and diversity of expertise, experience, and perspectives to undertake this review with the quality and credibility needed.
- Page 37, lines 1-3: regarding peer review and public participation: "Worthwhile public comments and suggestions for improving the ISA's methods, soundness, and clarity have been repeatedly ignored over the past decade." This is a sweeping generalization that is unsupported. What exactly are the "worthwhile public comments and suggestions"? Who made them? In what way are they worthwhile? To the extent that they have been "ignored," might there be some reason (e.g., infeasible to implement given resource and time constraints, or out of scope)?
- Page 37, lines 9-11: "The peer review and public participation processes should be changed to better and more quickly incorporate useful technical suggestions from outside the EPA/CASAC community." What is the basis for this statement? What deliberations at CASAC's public meeting underly this statement? The NAAQS review process was redesigned in 2006, with adjustments in 2007 and 2009, to explicitly provide opportunities for the public to provide input via a kick-off workshop, followed by a sequence of

public meetings as a staggered series of documents were developed, reviewed, and revised. That process was thrown out, without input from EPA career staff, public input from CASAC, or input from the public, by Administrators Pruitt and Wheeler. How would public input be "more quickly" incorporated? It is not clear what CASAC is recommending here, nor the basis of this recommendation. Either provide specifics or delete this. A simple way to improve the current process is to undue all of the adverse ad hoc changes to the review process imposed by Administrators Pruitt and Wheeler.

- Page 37, line 19: while there is merit to some of this paragraph, the statement that "The experts should come primarily from outside the air pollution health effects area" is not helpful. There are domain-specific issues related to air pollution health effects that are not shared with many other health effects domains. For examples, randomized controlled trials that underlie many FDA decisions are not possible with air pollution.
- Page 37, line 20-23: "Much recent and current research from the air pollution health effects community lags by decades other areas of applied science, engineering, epidemiology, and risk analysis in understanding and appropriately applying modern methods and processes of causal analysis, quantitative risk modeling and management science useful for regulatory risk assessment and science-based risk regulation." While this statement seems to represent the personal opinion of the chair of CASAC, it is not clear that it is a trustworthy statement in general. For example, arguably, there is "appropriate" application (or non-application) of methods that are (are not) relevant to linkages between air pollution and health effects. Each member of CASAC should carefully consider if they want to sign their name to this statement. If not, it can be put in context or it can remain with individual comments of members who wish to make this statement.

#### Comments on CASAC's Draft Letter on EPA's Draft Policy Assessment

#### Letter

- CASAC should begin the letter by acknowledging that it lacks the breadth, depth, and diversity of expertise, experience, and perspectives to provide the scope and depth of review of the primary and secondary ozone standards and that this situation is because the EPA Administrator declined to appoint an appropriately constituted CASAC Ozone Review Panel.
- CASAC should caveat its letter by pointing out that, without the needed breadth, depth, and diversity of expertise, experience, and perspectives, it cannot credibly provide advice on issues that are outside its domain areas of expertise. An example is epidemiology.

- Furthermore, even in areas for which CASAC has some expertise, such as controlled human studies, toxicology, and ecological effects to wildlife, it lacks diversity of expertise, experience, and perspectives that comes from having multiple experts in key areas. This is not a limitation of any individual member of CASAC. Rather, this is a process limitation inappropriately imposed on CASAC by the EPA Administrator.
- As a matter of credible professional practice, an advisory group such as CASAC should acknowledge its own limitations before attempting to develop advice that it is not adequately constituted to give.
- Page 1, Lines 29-30. CASAC should point out that the ad hoc pool of consultants does not adequately substitute for an appropriately appointed CASAC Ozone Review Panel. Members of a panel should be appointed by the SAB Staff Office, not by the Administrator, to avoid the appearance -- if not reality -- of conflict of interest. Information is now publicly available that many members of the ad hoc pool of consultants were either nominated by sitting members of the chartered CASAC or have ties to regulated industries.<sup>15</sup> This gives the appearance of lack of impartiality. It also facilitates cherry-picking and circular logical fallacies that "some members" of the pool of consultants agree with the points of view of some members of CASAC which appears to be by design given how appointments were made.
- Page 1, lines 34-39: CASAC substantially over-states its critique of the draft ISA by over-generalizing. For example, although CASAC argues that some causal determinations are not adequately founded or explained, it is not the case that all of the causal determinations lack foundation or explanation. The draft ISA does provide a comprehensive, systematic assessment but can be improved, as is often the case with a first draft. It is not uncommon that a few new causal determinations in a first draft of an ISA might need to be reconsidered: this does not mean that the entire document is not trustworthy.
- Based on a full reading of CASAC's letter and consensus responses to charge
  questions, it appears that CASAC has failed to give proper consideration to atrisk populations. In the last review, CASAC found that a level of 70 ppb provides
  little to no margin of safety, and advised the administrator that lower levels down
  to 60 ppb are justified by the scientific evidence and would provide margins of
  safety. Levels lower than the current standard would provide additional margin of
  safety, particularly for at-risk populations such as asthmatic children or outdoor
  workers.
- Page 2, lines 2-4: that "the available evidence does not reasonably call into question the adequacy of the current secondary ozone standards and concurs

<sup>&</sup>lt;sup>15</sup> Reilly, S., "Documents expose ties among EPA panel's experts," E&E News, Friday, February 7, 2020.

that they should be retained" appears to have been arrived at based on the expertise of only one member of CASAC. In the prior ozone review, there were multiple experts who provide breadth, depth, and diversity of expertise in areas related to effects on plants. The current review appropriately also touches upon wildlife. However, unfortunately, the Admininstrator has deprived CASAC as an advisory body of credibility to conduct a thorough and accurate review of ecological effects by depriving CASAC of an appropriately constituted review panel.

- Page 2, line 10: while a National Academy review of the process by which EPA conducts scientific reviews of NAAQS would be valuable, it is untenable to imply that such a review should be limited to persons from outside of the "NAAQS community" if this implies not including experts in air quality, exposure measurement and modeling, controlled human studies, toxicology, and epidemiology related to air quality. The outcome of a review conducted solely by persons "outside of the NAAQS community" would likely be untethered to realities of salient characteristics of data pertaining to air quality and effects. Of course, there can be value in bringing in new methodological perspectives, but this should not be to the exclusion of domain expertise.
- Page 2, lines 18 to 23: the list here is not parallel. Items (a) to (c) relate to process issues. However, item (d) is not a process issue: it is a matter of self-perceived topical focus of CASAC. The implication of item (d) is that this is somehow new or unique in some special way. Yet, in prior years, with different members, CASAC has given explicit consideration to associational versus biological and other bases for causal conclusions, and reexamination of frameworks used in previous reviews. Thus, there is nothing unique here from a process or procedural perspective.
- Page 2, lines 34-42: CASAC should emphasize in the first sentence that it is being asked to review a draft PA <u>simultaneously</u> with the draft ISA. This situation was intentionally designed <u>out</u> of the NAAQS review process in 2006, but has been recently introduced by Administrators Pruitt and Wheeler. As noted earlier in these comments and in my prior comments, it is inappropriate to commingle science and policy review. There is the obvious problem that unresolved scientific issues from review of the draft ISA can have implications for needed revisions of the PA. There is the more pernicious possibility that the ISA could be revised to be consistent with policy outcomes in the PA. Sequencing the documents so that the ISA is reviewed and finalized before the PA is reviewed and finalized prevents this potential pernicious outcome.
- Page 2, same paragraph. CASAC should acknowledge that the evidence-based and risk-based approaches provide different information. In the case of ozone, the evidence-based approach tends to focus on controlled human studies.
   Judgments can be made regarding the validity of risk estimates. However, such

- judgments would have to be made by an appropriately constituted CASAC Ozone Review panel, that has the needed breadth, depth, and diversity of expertise, experience, and perspectives.
- Page 3, lines 4-5. The CASAC appears to have only one expert in ecological effects. As such, CASAC lacks the breadth, depth, and diversity of expertise, experience, and perspectives necessary to advise EPA regarding the secondary standard.
- Page 3, lines 6-8: It is not clear that CASAC has any expertise related to the
  effect of ozone on climate, much less how realistic CASAC's recommendation is
  for providing quantitative estimates and uncertainty bands for the effects of
  ozone. Advice offered outside of its core areas of competence undermines the
  credibility of CASAC. CASAC should state that it was not augmented with an
  Ozone Review Panel and is not able to credibly advise on this matter.
- CASAC should recommend that an Ozone Review Panel be appointed by the EPA SAB Staff Office prior to review of the second draft of the PA, and that the second draft of the PA should be reviewed only after it has incorporated changes in the final draft of the ISA.

#### **Consensus Statements**

- Page 1, lines 11-13: CASAC should go farther here. It is not just "unusual," it is "inappropriate". See also earlier comments (above) on this matter.
- Page 1, line 22: change "consider restoring" to "restore"
- Page 1, lines 25-26: The risk of groupthink, confirmation and conformation baises, and other biases are more pronounced in a smaller group with a domineering chair. For example:
  - Several CASAC members appear to have been appointed by Administrators Pruitt and Wheeler based on the consistency of their prior stated views with policy outcomes sought by the political appointees. Members with previous publicly stated policy positions on issues such as the ozone review might be unlikely to contradict their prior statements and thus would selectively look for confirmation of their previously stated views.
  - The ad-hoc pool of consultants includes several members with ties to sitting CASAC members, which not only provides an opportunity for cherry-picking (as evident in repeated references in CASAC's draft letters on the draft ISA and the draft PA) of consultant comments favorable to the positions of the sitting members, but enhances overall groupthink.
  - Some members of the group may be overwhelmed by the repetitive lecturing and persistent questioning (the fallacy of many questions) of a domineering chair. For example, members who don't agree with the chair have, from time

to time, been asked to justify their disagreement with the chair, during CASAC proceedings, whereas members who agree with the chair have not typically been subject to similar questioning by the chair. The chair has augmented EPA charge questions with his own sets of questions and implied that members of the CASAC and of the ad hoc pool should answer extensive questions posed by the chair. This can lead to conformance to the views of the chair that might not otherwise have occurred. In many cases, the use of these techniques have not been offered to other members of CASAC (i.e. other members of CASAC were not offered lecture time during public meetings, nor offered the opportunity to systematically cross-examine other members).

- The CASAC suffers from availability biases related to lack of domain expertise. Because of its lack of breadth, depth, and diversity of expertise, experience, and perspectives, the CASAC is not able to condition its judgments on the relevant scientific evidence and inference methods. In this situation, the biases can be exacerbated by focusing only on evidence and methods selectively emphasized by some members of the group.
- The lack of breadth, depth, and diversity of expertise, experience, and perspectives is clearly highlighted by the dearth of CASAC discussants assigned to each of EPA's charge questions. In past reviews, there were typically a larger number of discussants for each charge question.
- CASAC is engaging in the fallacy of appeal to authority and fallacy of vagueness in making vague appeals to authority such as on page 2, lines 32 and 38 ("external experts and many public commentators" and "even to expert readers", respectively). These vague statements give the impression of widespread concern when in fact these may represent the views only of a few people, possibly including some with the potential for motivational biases. CASAC should make statements about its findings based on evidence and logical inference, not vague appeals to authority. The latter are not trustworthy.
- Page 2, lines 18-29: As noted in comments above, claims that CASAC is interested in association as distinct from biological plausibility are not novel or new. CASAC has also previously examined frameworks used in previous reviews. Thus, none of the points here are novel, nor are they process issues. Part (d) should be deleted.
- Page 2, line 25: "Statistical association vs. biological (mechanistic) concepts of causation": there is nothing new here in terms of the idea of considering biological mechanisms. This is a strawman fallacy, with the misleading implication that CASAC hasn't done this before. The current CASAC may be looking at issues from a different (normatively risk-seeking) perspective compared to past CASACs, but this is not a difference in process.

- Page 2, line 26-27: How does CASAC handle the situation in which there are not directly relevant data? For example, given that there are not controlled human studies of asthmatic children, does CASAC simply find that absence of evidence means evidence of absence (a fallacy) or does CASAC make expert judgment regarding the plausibility that asthmatic children may be at-risk taking into account other evidence and inference approaches?
- o Page 3, lines 1-25: "Changes" in ozone concentrations occur over time because of control strategies (e.g., vehicle fleet turnover in which older higher emitting vehicles are replaced with new lower emitting vehicles). Differences in ozone concentrations occur spatially because of varying contributions from different types of emission sources and varying status of control program implementation. This is not acknowledged by the CASAC. The general tone of the "measures" listed here are that CASAC wants to impose a normatively risk-seeking burden of proof for hazard and concentration-response far beyond that required by the statute. The basis for CASAC's recommendation for a quantitative treatment of the effects of ozone on climate change are puzzling, given that CASAC does not have expertise in this area.
- CASAC should recommend that EPA allow more time to develop documents and for iterative review and revision of documents, and that the ISA should be finalized before the final review of the PA.
- Page 4, lines 40 to end of page, and to the top of the next page: This is a recommendation for future monitoring. As such, this does not belong in a section that is about comments on the draft PA.
- Page 7, lines 15-16 ("what fraction of the population (particularly at-risk populations if possible) is expected to spend 6.6 hours or more outdoors at moderate exertion"): An obvious answer is that outdoor workers are a population that is likely to spend this amount of time outdoors at moderate exertion. CASAC should not reach a conclusion about the current standard without explicit consideration of at-risk populations. Other at-risk populations include, for example, asthmatic children. The current chair of CASAC wrote in a Wall Street Journal op-ed in 2015: "The cynical use of asthma patients to promote a proregulation political agenda that won't actually help them undermines the credibility of regulatory science and damages the public interest." That the chair of CASAC would assign a cynical motive to concern over asthmatic children is its own statement, but the fact that the CASAC under this chair seems unconcerned with at-risk populations while consistent with the chair's prior publicly stated views is contrary to the intent of the Clean Air Act as interpreted by case law and as set forth by EPA staff in the draft PA.
- Page 7, lines 20-22 "(Public Health Implications and At-Risk Populations) lacks adequate discussion about greater susceptibility for minority and/or lower

socioeconomic status (SES) populations.": In what way, if at all, has CASAC taken this into account greater susceptibility for minority and/or lower socioeconomic status (SES) populations in arriving at judgments regarding atrisk populations and whether the current standard protects such populations with an adequate margin of safety?

 Page 8, lines 37-39: "The risk assessments are based almost exclusively on studies in healthy adults and make unverified assumptions about ozone health effects in children with asthma." This statement illustrates a problem with groupthink of the current CASAC. Of course controlled human studies are mostly going to be with health adult subjects. Imagine trying to get IRB approval for a controlled human study on severely asthmatic children. There are not going to be controlled human studies on subpopulations that are highly at-risk. However, absence of this evidence does not imply evidence of absence of an effect. Credible domain experts, using relevant data and inference methods (rational lines of inference) can formulate judgments regarding such subpopulations. The subjectivity of such judgments is an appropriate subject of peer review. This is precisely why CASAC must be augmented with an appropriately appointed Ozone Review Panel, so that it has the breadth, depth, and diversity of expertise, experience, and perspectives relevant to a critical review of the subject matter. This text is also puzzling given that it is followed by a detailed mechanistic discussion of ways in which asthma can be exacerbated based on ozone exposure. However, the discussion of asthma exacerbation appears to be ignored by the CASAC when formulating its finding that the current standard is adequate to protect public health. CASAC is failing to inform the Administrator of at-risk subpopulations for which the current standard may not (or does not) provide an adequate margin of safety (e.g., asthmatic children susceptible to asthma exacerbation, outdoor workers).

#### o Page 10, lines 6-11:

None of the low-concentration, 6- to 7-hr studies listed in Tables 3A-1 and 3A-2 included people with asthma. Very few clinical studies have included severe or even moderate asthma, let alone children with asthma, and none have included people with unstable asthma or those prone to exacerbations. This is a key knowledge gap and raises legitimate questions about whether the current standard provides an adequate margin of safety for people with asthma

This text is very important. In fact, this was a key concern in the prior review cycle for ozone as well. Yet, in this review cycle, other than being mentioned on page 10 of the consensus statement, this finding appears not to be considered by the CASAC as a whole in arriving at its advice for the Administrator. As such, CASAC is making policy advice, not science advice. The CASAC should elevate

- this statement to the main letter and advise the Administrator on implications for setting a standard that protects public health with an adequate margin of safety, not just for the general public but also for at-risk groups.
- Page 12, lines 12-14: Reductions in NO<sub>x</sub> emissions are likely the combined effect of reduction in coal-fired power plant emissions and reduction in onroad vehicle emissions as a result of fleet turnover.
- Page 13, lines 38-43. Not clear in this statement is whether the members of CASAC who claim that available evidence does not call into question the adequacy of the current standard have explicitly taken at-risk populations into account. Is the disparity in findings among CASAC members merely because some member have taken at-risk populations into account, while others have not?
- Also related to Page 13, lines 38-43, CASAC could conceivably find that the current standard protects public health but does not do so with an adequate margin of safety for either the general population or for at-risk groups. To inform the Administrator, CASAC should offer advice regarding alternative standards that would be scientifically justifiable in terms of reducing the frequency or severity of adverse effects while also providing a greater margin of safety. For example, in the last review cycle, CASAC recommended levels below 70 ppb down to 60 ppb, while retaining the current form of the primary standard. What levels would this CASAC recommend for consideration by the Administrator? Or is CASAC completely certain that the current standard provides an adequate margin of safety for at-risk groups?
- Page 14, line 12: Research on control strategies would no doubt be useful but it outside the scope of NAAQS review. This is an implementation issue. If CASAC wants to offer policy advice on implementation, it should do so separately from its advice on recommended levels of the standard.
- Page 15: In the last review, CASAC recommended a different form (a one year average of the W126) than what was adopted by EPA. In August 2019 the Court of Appeals for the District of Columbia Circuit remanded the 2015 secondary ozone standard to EPA for further justification or revision. This CASAC does not have breadth and diversity of expertise on relative yield loss, relative biomass loss, and foliar injury, which are the pertinent adverse effect endpoints in the previous review. CASAC should acknowledge that it was not able to review these issues with the breadth and diversity of expertise necessary to such a review, and that CASAC should be augmented with an Ozone Review Panel that includes the needed expertise prior to review of a second draft of the PA.
- Page 18: lines 38 to 43: Who on CASAC has expertise in the effects of ozone on radiative forcing? It appears that CASAC lacks relevant expertise and therefore lacks credibility to offer advice here. CASAC should simply state that it did not

- have the expertise to review this material. CASAC should recommend that CASAC should be augmented with an Ozone Review Panel that includes the needed expertise prior to review of a second draft of the PA.
- Page 22, lines 16-17: CASAC was emphatic in its 2014 advice to EPA that a three-year average of a seasonal W126 index was not protective unless the level was set downward to account for inter-annual variability. The issue of year-toyear variability was of significant concern because a bad year during the three year averaging period would lead to disproportionate damage. Hence, CASAC advise that the form be based on an annual, not three-year, average of the seasonal W126 index.
- Page 25: lines 4-8: Who on CASAC has expertise in the effects of ozone on radiative forcing? It appears that CASAC lacks relevant expertise and therefore lacks credibility to offer advice here. CASAC should simply state that it did not have the expertise to review this material. CASAC should recommend that CASAC should be augmented with an Ozone Review Panel that includes the needed expertise prior to review of a second draft of the PA.